DEPARTMENT OF HEALTH AND HUMAN SERVICES

91060d

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

March 27, 2001

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 01-40

Brian Phuong, President
Happy Tofu, Inc.
6113 NE 92nd Drive
Portland, Oregon 97220

WARNING LETTER

Dear Mr. Phuong:

The Food and Drug Administration (FDA) conducted an inspection of your tofu manufacturing facility located at 6113 NE 92nd Drive, Portland, Oregon, on February 12-13, 2001. The inspection revealed numerous deviations from the Good Manufacturing Practice (GMP) regulations, Title 21, Code of Federal Regulations (21 CFR) Part 110. At the conclusion of the inspection, you were issued a Form FDA-483 (copy enclosed) which delineated a number of insanitary conditions present in your facility at the time of the inspection. These conditions cause the tofu produced in this facility to be adulterated within the meaning of Section 402(a)(4), (copy enclosed) of the Federal Food, Drug, and Cosmetic Act (the Act), in that they were prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth. You can find this Act through links in FDA's homepage at www.fda.gov.

The following is a list of the insanitary conditions observed by our investigators during the inspection:

1. Eighteen fresh and five dried insect larvae were found on four pallets of 60 lbs. paper bags of [redacted] Soybeans between the bag surfaces and shrink wrap. Also, numerous insect fragments were found between the shrink-wrap and surfaces of several paper bags.

2. Employees were observed performing cleaning operations and touching nonfood contact surfaces, then returning to their workstations and handling product without washing hands.

3. No backflow prevention device on one hose connection where the hose end was submerged in a tofu soaking tank.

4. No backflow prevention device on two faucets which have hose connections.

5. Structural deficiencies including rust on table surface where buckets used for holding tofu are being stored, and ½ inch gap underneath roll up door.

Based on these observation, it is evident you have sanitation problems in your facility. It is your responsibility to have an effective, ongoing sanitation program, which eliminates the insanitary conditions we have observed.

The above violations are not meant to be an all-inclusive list of deficiencies in your facility. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa Elrand, Compliance Officer at (425) 483-4913 or via e-mail at lelrand@ora.fda.gov.

Sincerely,

Charles M. Breen
District Director

Enclosures:
Form FDA 483 –2/13/01
21 CFR PART 110
Section 402 (a)(4) of the Federal Food, Drug, and Cosmetic Act

cc: OSDA with disclosure statement